REMARKS

Claim Status

Rejection Under 35 USC §102(b)

Claims 1, 2, 4, 7-11 and 15-17 are rejected under 35 USC §102(b) as being anticipated by US Patent No. 5,002,777 to Cuca, ("Cuca"). The Examiner asserts that Cuca discloses, in Example 1, a soft gel encapsulated antacid suspension formulation which contains about 66% calcium carbonate as the active agent, about 0.5% carboxymethylcellulose sodium (CMC-Na) as the stabilizing agent and about 33% polyethylene glycol (PEG-400) as the solvent.

The Examiner asserts that CMC is known and defined as a suspension stabilizer; water is disclosed as part of the composition, the presence of which is further defined by Claim 1 of Cuca to be less than about 5% by weight of the composition. The Examiner asserts that the Example also discloses making the pourable fill composition as well as encapsulating it in a soft shell capsule.

The Applicants respectfully traverse the rejection. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Cuca discloses a concentrated suspension of calcium carbonate particles in a liquid carrier that is compatible with a capsule shell material. Cuca attempts to overcome the problems associated with attempting to put aqueous liquid suspensions in gelatin capsules – such as deformation and/or rupture of the capsule. Additionally, concentrated suspensions of calcium carbonate were known to be difficult to pump. Cuca discloses that pumping problems could be due to the generally spherical shape of the particles of most conventional calcium carbonate preparations. Cuca thus requires that the calcium carbonate particles used *must* not only have a particular particle size distribution, but they must be irregularly shaped and have a plurality of edges formed by the intersection of substantially planar surfaces. Preferably at least about 65% of the particles of calcium

carbonate should be in the range of from about 1 to about 10 microns, and preferably from about 70% to about 90% or more. Thus, Cuca discloses very particular compositions containing irregularly shaped calcium carbonate particles at a particular size distribution. Cuca discloses only calcium carbonate compositions, with only PEG used as a liquid carrier, and CMC used as a suspending agent.

The present Claims, as amended, recite elements not disclosed by Cuca, namely, a stabilizer selected from the group consisting of phytic acid, disodium salts of ethylene diamine tetraacetic acid, calcium salts of ethylene diamine tetraacetic acid, tetrasodium ethylene diamine tetraacetic acid, sodium hexametaphosphate, di(hydroxyethyl)glycine, 8-hydroxyquinoline, and mixtures thereof.

The Applicants respectfully submit that Cuca does not disclose each and every element set forth in the Claims, as amended, and thus, as a matter of law, cannot anticipate the Claims. Therefore, the Applicants respectfully request that the rejection be withdrawn.

Rejection Under 35 USC §103(a)

Claims 1-17 are rejected under 35 USC §103(a) as being unpatentable over US Patent No. 6,001,392 to Wen et al. ("Wen"). The Examiner asserts that Wen discloses, in Claim 1, a sustained release composition whose coated portion contains 20-80% by weight of a suspended pharmaceutical active (i.e. drug/resin complex). The active may be an antitussive such as dextromethorphan or other type such as analgesic, anti-inflammatory, or antipyretic. Stabilizing agents such as methylparaben and propylparaben are disclosed in the formulation at 0.08% and 0.05% respectively in the examples. The Examiner asserts that other preservatives, such as disodium EDTA are disclosed as being functionally equivalent to the formulation, and that polyethylene glycol (PEG) and water are also disclosed. The Examiner asserts that methods of preparation are disclosed in Example 1 and preparation of the composition as encapsulated liquid suspensions is disclosed.

The Examiner acknowledges that Wen does not specifically teach disodium EDTA, PEG or water within the Applicants' claimed ranges. However, the Examiner asserts that

because the values of these components are adjustable, each is a result-effective parameter that a person of skill in the art would routinely optimize. The Examiner further asserts that optimization of parameters is a routine practice that would be obvious, and that one of skill in the art would be motivated to substitute disodium EDTA as a functionally equivalent preservative to methyl- and/or propyl paraben to expect to successfully achieve the desired encapsulated pharmaceutically active suspension.

The Applicants respectfully traverse the rejection. The Examiner has not met the burden of establishing a *prima facie* case of obviousness. See MPEP § 2143.01. "Citing a reference that merely indicates that isolated elements and/or features recited in the claims are known is not sufficient basis for concluding that the combination of claimed elements would be obvious." *See Ex parte Hiyamizu*, 10 U.S.P.Q. 2D (BNA) 1393, 1394 (1988). "Determinations of obviousness can not be based on the hindsight combination of components selectively culled from the prior art to fit parameters." *See ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 48 USPQ2d 1321 (Fed. Cir. 1998). "There should be something in the prior art or a convincing line of reasoning in the answer suggesting the desirability of combining the reference in such a manner as to arrive at the claimed invention." *In re Dembiczak* 175 F. 3d 994, 999 (Fed. Cir. 1999). Even in light of *KSR v. Teleflex* 127 S.Ct. 1727 (2007), in order for an obviousness rejection to stand, there should at least be some need or predictability in the achieved result, considering the common sense of one of ordinary skill in the art.

Wen discloses a mixture of coated and non-coated sulfonic cation exchange resins cross-linked with about 8% divinyl benzene onto which dextrmethorphan has been loaded. The ratio of coated and uncoated drug/resin complexes is about 55/45. Wen discloses antitussives, antihistamines, sympathomimetic drugs, analgesics, anti-inflammatory drugs, couth suppressants and/or expectorants. Wen also discloses the use of carriers and excipients such as diluents, binders and adhesives , as well as lubricants, solublizers, humectants, disintegrants, colorants, flavorings, preservatives, sweeteners and miscellaneous materials such as buffers and adsorbents. Humectants disclosed include polyethylene glycol (PEG). Preservatives disclosed include disodium EDTA. Wen discloses aqueous and non-aqueous suspensions.

As the Examiner acknowledges, Wen does not specifically teach disodium EDTA, PEG or water within the Applicants' claimed ranges.

PEG is disclosed at amounts of from about 5% to about 20% because PEG is used as a humectant in Wen. PEG is included as a solvent in the present Claims. Because PEG is used for different uses/functions in Wen vs. the present invention, the Applicants submit that PEG is therefore not simply a result effective parameter to be optimized. The amount of PEG useful as a solvent may well be different than that useful as a humectant. Wen provides no teaching, suggestion, motivation, predictability or expectation of success, particularly in the unpredictable chemical and pharmaceutical arts, for an amount of PEG that might be useful as a solvent. Therefore, the Applicants assert that it would not have been obvious from Wen to have arrived at the Applicants' recited amounts of solvent.

Similarly, EDTA is disclosed in Wen as a preservative, not a stabilizer as in the present Claims. Furthermore, there is *no* amount of EDTA or similar preservative disclosed *at all* in Wen. The cited column 7, lines 60-65 do not disclose any amount of preservative that would be useful in the composition of Wen. Rather, only ratios of methyl paraben to propyl paraben are disclosed. In addition, none of the working examples provided by Wen include EDTA or similar preservatives. Only parabens are shown in the examples. Therefore, the Applicants assert that EDTA is not simply a result effective parameter to be optimized. Wen provides no teaching, suggestion, motivation, predictability or expectation of success, particularly in the unpredictable chemical and pharmaceutical arts, for any amount of EDTA or similar compound in a composition such as Claimed in the present Application. In addition, Wen specifically states that each preservative must be evaluated in each formulation, thus explicitly providing no direction for what a useful or effective amount of preservative might be. Therefore, the Applicants assert that it would not have been obvious from Wen to have arrived at the Applicants' recited amounts of suspended stabilizing agent.

Because Wen does not provide any teaching, suggestion, motivation, predictability or expectation of success for the particular types and amounts of stabilizer and solvent of the

present invention, the Applicants assert that the Claims, as amended are non-obvious over Wen, and respectfully request that the rejection be withdrawn.

Conclusion

This response represents an earnest effort to place the present application in proper form, to distinguish the Claims from the cited documents, and to overcome the rejections. In view of the foregoing, entry of the amendments presented herein, reconsideration of this application, and allowance of all pending claims are respectfully requested.

Respectfully submitted,

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